

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problems Mailbox.**

THIS PAGE BLANK (USPTO)

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61M 15/00		A2	(11) International Publication Number: WO 91/19524 (43) International Publication Date: 26 December 1991 (26.12.91)
(21) International Application Number: PCT/GB91/00958 (22) International Filing Date: 14 June 1991 (14.06.91)		(74) Agents: BARLOW, Roy, James et al.; J. A. Kemp & Co., 14, South Square, Gray's Inn, London WC1R 5LX (GB).	
(30) Priority data: 9013261.4 14 June 1990 (14.06.90) GB 9106612.6 28 March 1991 (28.03.91) GB		(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FI, FR (European patent), GB (European patent), GR (European patent), HU, IT (European patent), JP, KR, LU (European patent), NL (European patent), NO, PL, SE (European patent), SU, US.	
(71) Applicant (for all designated States except US): RHONE-POULENC RORER LIMITED [GB/GB]; Rainham Road South, Dagenham, Essex RM10 7XS (GB). (72) Inventors; and (75) Inventors/Applicants (for US only) : CALVERT, John, Richard [GB/GB]; COOK, Robert, Stanley [GB/GB]; HOBBS, Michael, Anthony [GB/GB]; LEIGHTON, Anne-Marie [GB/GB]; SIMPKIN, Gordon, Thomas [GB/GB]; TRUNLEY, Roy [GB/GB]; WEST, Anthony, Douglas [GB/GB]; Rhone-Poulen Rorer Limited, Rainham Road South, Dagenham, Essex RM10 7XS (GB).		Published <i>Without international search report and to be republished upon receipt of that report.</i>	
(54) Title: INHALER			
(57) Abstract An inhaler for inhaling pulverulent medicament from within a capsule comprises a chamber (24) within which the capsule is positioned with its longitudinal axis in the median plane of the chamber and thus generally parallel to the front (29) and rear walls (30) of the chamber, where the spacing between said front and rear walls is just greater than the diameter of the capsule and the diameter of the chamber is larger than the capsule's length. The device includes pins (21) serving as opening means to pierce the ends of the capsule while it is seated in a recess (25). Air inlets (26), chamber (24) and mouthpiece (27) are in such a spatial relation as to create a swirling or vortexing movement of the airflow which allows good capsule's emptying and powders to be finely dispersed. Chamber and mouthpiece inner walls can be of antistatic material.			

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BP	Burkina Faso	GB	United Kingdom	MW	Malawi
BC	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SN	Senegal
CI	Côte d'Ivoire	LI	Liechtenstein	SU	Soviet Union
CM	Cameroon	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
DE	Germany	MC	Monaco	US	United States of America
DK	Denmark				

- 1 -

Inhaler

The present invention relates to an inhaler for the inhalation of a medicament, usually pulverulent, from a capsule.

5 Various forms of inhaler are already known, and among these are the ones in which the capsule is pierced, usually at the ends, in order to allow the medicament to be withdrawn during inhalation, and those in which the cap portion of the capsule is removed from the body portion in 10 order to allow the medicament to be extracted.

Extraction of the medicament usually occurs as a result of the inhaled airstream passing over or through the capsule.

With both of the above types of inhaler, it is 15 known to allow the airstream passing through the inhaler to adopt a vertical configuration which results in the pierced capsule or the separated capsule cap and body portions tumbling in the airstream.

It is a disadvantage of virtually all of the known 20 inhalers that not all of the medicament is withdrawn from the capsule or the separated capsule cap and body portions, and this is frequently because the capsule portions or the capsule as a whole can become lodged in the inhaler in a position where either the extraction effect of the 25 inhalation air is unable to operate effectively or the capsule or capsule cap and body portions can become prevented from tumbling freely by a mechanical constraint.

It is an object of the present invention to provide an inhaler in which the disadvantages mentioned above are 30 eliminated.

In accordance with one aspect of the present invention there is provided an inhaler which comprises a chamber defined by (a) first and second generally parallel spaced opposed walls defining a median plane of said chamber 35 mid-way therebetween, and between which parallel spaced

- 2 -

walls the capsule can fit with its longitudinal axis generally parallel to said first and second walls but in any angular orientation, and (b) at least one peripheral wall; an exhaust nozzle through which air can be exhausted from
5 said chamber by inhalation; at least one air inlet arranged in relation to the exhaust nozzle to generate in the chamber during inhalation an airflow rotating about an axis generally perpendicular to said first and second walls; and holding means in the inhaler in association with means
10 operable from outside the closed chamber for opening a capsule while held in the holding means with the longitudinal axis of the capsule perpendicular to said axis, wherein the holding means are effective to hold a capsule having a length greater than the minimum spacing between
15 first and second walls and less than the minimum cross-sectional dimension of said chamber when viewed parallel to said axis of rotation and is configured to hold a capsule with its axis of symmetry substantially coincident with the median plane of said chamber, and to hold a capsule having a
20 diameter less than said minimum spacing between the first and second walls.

A second aspect of the present invention provides an inhaler which comprises a chamber defined by (a) first and second generally parallel spaced opposed walls between
25 which the capsule can fit with its longitudinal axis generally parallel to said first and second walls but in any angular orientation, and (b) at least one further wall; an exhaust nozzle through which air can be exhausted from said chamber by inhalation; at least one air inlet arranged in relation to the exhaust nozzle to generate in the chamber during inhalation an airflow rotating about an axis generally perpendicular to said first and second walls; and a recess in the inhaler in association with means for
30 opening a capsule while held in the recess with the longitudinal axis of the capsule perpendicular to said axis,
35 wherein the opening means are effective to open a capsule

- 3 -

having a length greater than the minimum spacing between said first and second walls and less than the minimum cross-sectional dimension of said chamber when viewed parallel to said axis of rotation, and to open a capsule having a
5 diameter less than said minimum spacing between the first and second walls; and wherein the chamber is non-circular and is able to allow the capsule to rotate freely about its transverse axis under the influence of the inhaled airstream and to impact against said at least one further wall in
10 order to increase the likelihood of ejection of the medicament from within the capsule.

A third aspect of the invention provides an inhaler comprising a mouthpiece; and a swirling chamber to receive a container which can be agitated, when open, in an inhalation
15 airstream to release powdered medicament from the interior of the container; wherein the chamber has walls defined of an anti-static member having a surface resistivity of less than 10^{12} Ohms.

In order that the present invention may more
20 readily be understood the following description is given, merely by way of example, reference being made to the accompanying drawings, in which:-

FIGURE 1 is a side elevational view of an inhaler in accordance with the present invention;

25 FIGURE 2 is a transverse sectional view of the inhaler of Figure 1;

FIGURE 3 is a sectional view taken on the line 3-3 of Figure 2, with the capsule in position ready for opening by the opening means;

30 FIGURE 4 is a view similar to Figure 3 but showing the inhaler slightly later during the operating cycle in which the capsule has just been opened;

FIGURE 5 is a view, again similar to Figure 3, but this time showing the two separated capsule portions in the
35 chamber being tumbled to remove the contained medicament;

FIGURE 6 is an underneath plan view showing the

- 4 -

rear casing, with an optional hinged cover to facilitate loading of a capsule to be opened;

FIGURE 7 is a sectional view of an alternative embodiment of inhaler of the pin-piercing type;

5 FIGURE 8 is a sectional view of the inhaler of Figure 7, taken on the line 8-8 of Figure 7;

FIGURE 9 is a sectional view taken on the line 9-9 of Figure 7;

10 FIGURE 10 is a sectional view of a third embodiment of inhaler;

FIGURE 11 is a sectional view taken on the line 11-11 of Figure 10;

FIGURE 12 is a sectional view taken on the line 12-12 of Figure 10;

15 FIGURE 13 is an elevational view of a further embodiment of inhaler in which the capsule is pierced by opening pins;

FIGURE 14 is a top plan view of the device of Figure 13;

20 FIGURE 15 is a section on the line 15-15 of Figure 13, showing the device in the capsule-receiving configuration;

FIGURE 16 is a view corresponding to Figure 15 but showing the device in the configuration in which the capsule 25 has just been ruptured;

FIGURE 17 is a section taken on the line 17-17 of Figure 13 but when in the configuration in which the capsule has just been ejected into the inhalation chamber;

30 FIGURE 18 is a section taken on the line 18-18 of Figure 15;

FIGURE 19 is a section taken on the line 19-19 of Figure 16; and

FIGURE 20 is a section taken on the line 20-20 of Figure 17.

35 Referring now to the drawings, Figure 1 shows a mouthpiece nozzle 1 on a plate 2 forming one wall of a

- 5 -

capsule-emptying chamber 3 (Figure 2).

The opposite wall of the chamber 3 is defined by a rear casing panel 4 which is removable in order to allow a capsule 5 to be inserted into the inhaler ready for opening.

5 The two parts of the device are held together by means of a bayonet system to be described later.

In register with the air passage 6 centrally within the mouthpiece nozzle 1 is a grid 7 which is preferably anti-static by virtue of a high electrical conductivity 10 and/or low surface resistivity, and/or high surface electrostatic dissipativity, through which grid the inhalation air passes but through which fragments of the capsule casing are unable to pass, and hence unable to enter the respiratory tract of the user.

15 Figure 2 shows an important characteristic of the present invention in that the cross-section of the capsule 5 is only slightly smaller than the minimum spacing between the planar right hand chamber wall (defined by the panel 2 and the screen 7) and the planar left hand chamber wall 20 (defined by the rear casing panel 4) with the result that both the capsule body 5a and the capsule cap 5b are prevented from adopting any other orientation than one in which their axes of symmetry are parallel to the planes of the left hand and right hand chamber walls.

25 It will of course be appreciated that the chamber 3 is defined not only by the left hand and right hand walls 4 and 7, respectively, but also by transversely extending walls such as the partition 8 shown in Figure 2.

30 Figure 1 illustrates an air inlet 9 which is one of several such inlets of the inhaler.

Figure 3 shows a sectional view taken on the line 3-3 of Figure 2, and illustrates not only the above-mentioned air inlet opening 9, but also two further air inlets 10 and 11, the functions of which will be described 35 below.

Figure 3 again shows the capsule 5 in position

- 6 -

ready for opening, with the capsule cap portion 5b held between an arcuate baffle 12 and an anvil 13. Alternatively the capsule could be positioned in the same manner except that the body portion 5a is squeezed between the baffle 12
5 and anvil 13 and the cap portion 5c will be removed by a knife 14 (Figure 4).

In this position the capsule 5 has its longitudinal axis in the median plane of the chamber, i.e. the plane perpendicular to the axis of symmetry and located mid-way
10 between the panels 2 and 4. The capsule is inserted into this position by sliding in a direction perpendicular to the plane of the paper of Figure 3, either with the rear casing panel 4 removed from the rest of the inhaler or by insertion through an optional insertion port to be described below
15 with reference to Figure 6.

Figure 3 also shows a capsule holding anvil 13 moulded integrally with the mouthpiece panel 2. Likewise, the arcuate baffle 12 is integrally moulded with the panel 2.

20 Rotatable relative to the arcuate baffle 12, by virtue of being moulded integrally with the rear casing panel 4, is an opening knife 14 which rotates in the clockwise direction during operation of the inhaler from the loading configuration to the inhalation configuration, so as
25 to flick the capsule body portion 5a away from the cap portion 5b, as shown in Figure 4 at the instant of separation of the capsule portions 5a and 5b.

Behind the opening knife 14 is a guide member 15 which, at the instant when a capsule ejector 16 also carried
30 by the rear casing panel 4 ejects the capsule cap portion 5b from between the baffle 12 and the anvil 13, as shown in Figure 5, cooperates with the anvil 13 to define a passage along which the portion of the capsule which has just been ejected from between the anvil 13 and the baffle 12 must
35 pass towards the inhalation chamber 3. This guiding action prevents the ejected capsule portion from being jammed. It

- 7 -

will also be appreciated that the trailing wall 19 on which the guide member 15 is formed also provides a near seal with the baffle 12, having the result that the majority of the inhalation air sweeps generally tangentially into the 5 chamber 3 by way of the inlet orifices 9 and 10, although the additional air inlet orifice 11 does allow a purge stream to pass along an arcuate passage 17 between the arcuate baffle 12 and an outer wall 18 of the inhaler, in order to purge the spacing between the baffle 12 and the 10 anvil 13 of any medicament which may have been spilt there as a result of the opening operation. The existence of this purge stream through the air inlet 11 therefore further enhances the degree of emptying of the medicament from the inhaler as a whole. The various inlets 9, 10 and 11 thus 15 contribute to the creation of a vertical airflow in the chamber 3.

It will of course be appreciated that there are three important criteria of the device in accordance with the present invention:-

20 (i) the pressure drop across the loaded inhaler, between inlet 9 or 10 and the inhalation mouthpiece 1 should be as low as possible;

(ii) there is a need for as near perfect as possible delivery of the medicament from within the capsule 25 in order to allow the medicament to enter the inhalation airstream; and

(iii) there is equally a need for as high as possible a degree of emptying of the device as a whole, because the efficiency of delivery of the medicament depends 30 not only upon the medicament being removed from the capsule but also upon the medicament actually reaching the respiratory tract of the user during inhalation.

The final position, shown in Figure 5, when the inhaler is in the relative rotational positioning of its two 35 major parts where the capsule has been opened and released into the spinning chamber 3 for capsule emptying, is the

- 8 -

only one in which the various air inlets 9, 10 and 11 all communicate with the interior of the device by means of the corresponding inlet gaps 9a, 10a and 11a respectively. In all other positions they are closed in that the ports are
5 not aligned until the capsule has been opened.

Figure 6 shows an alternative embodiment of the device in which the rear casing panel 4a includes a capsule insertion port with a hinged or push fit cover 20 which can be opened to facilitate insertion of a capsule 5 in order to
10 allow the device to be loaded without the need to separate the mouthpiece 1 and its panel 2 from the rear casing panel 4. However, these portions will nevertheless normally need to be separated at the end of the operating cycle in order to allow the spent capsule body and cap portions to be
15 removed and permit cleaning of the device by the user.

The bayonet system, mentioned above, for holding the two parts of the device together comprises a pin 17 on the exterior of the skirt of the mouthpiece member engageable in an axially extending slot 18 (Figure 1) in the
20 skirt of the rear panel part. This slot opens into a groove 19 running round the skirt of the rear panel over approximately 80° of arc of the rear panel part, so as to permit rotation of the rear panel part relative to the mouthpiece part without axial separation of these two parts.
25

In order to minimise the extent to which the released powdered medicament can agglomerate on the surface of the air passage through the inhaler, the panels 2, 4 and the partition 8 which define the chamber portion 3 may be formed of a polymer with a low surface resistivity, thereby
30 having anti-static properties. Preferably the material defining the inside wall of the chamber 3 is a polymer having a surface resistivity less than 10^{12} Ohms or more preferably less than 10^8 Ohms. In the present embodiment, the entire device is formed of the same polymer of low
35 surface resistivity, but if desired the chamber-defining walls may be provided with an inner lining of the polymer of

- 9 -

low surface resistivity.

There are various additives known to increase the anti-static properties of polymers, for example by increasing the electrical conductivity or reducing the 5 surface resistivity, or enhancing the static dissipativity properties. One possibility is to incorporate carbon or steel filler, often in the form of fibres, into the polymer used for manufacture of those components to be given enhanced anti-static properties. This enhances the 10 electrical conductivity and/or lowers the surface resistivity. Alternatively non-fibrous chemical additives, often blended into the moulding polymer in chip form prior to the moulding process, may be used to lower the surface resistivity in the moulded product. The product Pebax 15 manufactured by the company Atochem of France is a polyether block amide product which may be obtained in an anti-static grade by use of such additives. Alternative materials for this application include the Atmer range of polypropylenes, containing antistatic additives, manufactured by ICI.

20 Another possibility is for the moulded component to be coated with an electrically conducting layer which thus reduces the surface resistivity.

Preferably the surface resistivity is less than 10^{12} Ohms, and more preferably it is less than 10^8 Ohms.

25 More preferably the mouthpiece in any of the embodiments may have at least its inner wall formed of such a polymer of low surface resistivity.

As with the embodiments to be described below, the embodiment of Figures 1 to 6 is formed by injection 30 moulding. The above-mentioned polymeric material of low surface resistivity is itself capable of injection moulding to form the relevant parts of the device, or the whole of it.

Turning now to Figure 7, there will be seen an 35 alternative embodiment of the inhaler in accordance with the present invention in that in this case the capsule is not

- 10 -

opened by separation of its cap and body portions, but is instead pierced by pins in order to allow extraction of the contents by a combination of pneumatic action, centrifugal action, and impact of the pierced capsule with the lateral
5 wall of the swirling chamber.

Figure 7 shows two capsule piercing pins 21 operated by respective buttons 22 which are biased outwardly by means of helical compression springs 23.

For this purpose the chamber 24, having a
10 peripheral wall 24a adjoining flat end walls defined by a grid 30 and a wall of a plug 29 to be described below, also has in its peripheral wall a recess 25 defined by a bulge 25a in the wall 24a able to accommodate the capsule while it is in the median plane of the relatively flat chamber.
15

The chamber furthermore includes two air inlets 26 which clearly generate a swirling motion in the chamber, about an axis which is generally centrally of the main chamber and extends perpendicular to the plane of the paper in Figure 7, as air is aspirated through the mouthpiece
20 nozzle 27 shown in Figure 8 and 9.

The operation of the inhaler shown in Figures 7, 8 and 9 is relatively straightforward and is as follows.

Firstly, the inhaler is opened by separating the right hand body portion 28 from the left hand body portion
25 28' shown in Figure 8, so that a capsule can be inserted in the recess 25 of the chamber 24.

The push-buttons will at this stage be biased to their outward positions so that the two needles 21 are retracted from the capsule-receiving bulge 25a in the
30 chamber wall.

The device is then re-assembled by joining the body portions 28 and 28' in the Figure 8 configuration, with some detent means (not shown) in order to hold the two halves together in the assembled configuration.

35 Up to now the capsule is closed and the operator does not have to fiddle with either a pierced capsule or a

- 11 -

capsule whose cap portion has been separated from its body portion.

The operator then simply squeezes the two push-buttons 22 inwardly, in order to cause the needles 21 to
5 rupture the ends of the capsule in the recess 25, and then to release those push-buttons so that they can be biased outwardly again by the compression springs 23. The capsule is then free in the recess 25 ready for entrainment when inhalation starts.

10 The user then simply inhales through the mouthpiece 27 of Figures 8 and 9 to generate the necessary swirling airstream into the chamber 24 through the inlets 26, and this same swirling action will detach the capsule from the recess 25 in which it is a loose fit, and will cause the
15 capsule to rotate rapidly about the above-mentioned axis of rotation of the vortical swirling airflow in the chamber 24.

The fact that the capsule is of a length shorter than the diameter of the chamber 24 means that it is able to be spun around its transverse axis in the vortical airflow,
20 and yet at the same time because its length is nearly equal to that diameter it is able to contact the peripheral wall of the chamber 24 so as to sustain impacts which remove the pulverulent medicament from within the capsule by a percussive action.

25 This degree of impact with the walls of the chamber 24 is enhanced by the presence of the recess 25 which gives the chamber 24 a generally non-symmetrical or eccentric appearance, resulting in random and rapidly occurring impacts which augment the centrifugal emptying of the
30 spinning capsule shell.

When the inhalation is complete, the medicament will almost completely have been emptied from the capsule, and indeed from the chamber 24 by being exhausted through the air-pervious grid 30 defining one of the opposed flat
35 walls of the chamber 24 (the other wall being defined by a closure plug 29).

- 12 -

The inhaler can then either be opened immediately in order to remove the spent capsule, or opened only when the next inhalation is to be carried out.

Provided the inhaler is kept dry, and if the material chosen for all of the embodiments of the inhaler in accordance with the invention is one which has relatively low electrostatic attraction for the powder in the capsule, the inhaler will not need regular cleaning when used by the same patient (i.e. other than for considerations of hygiene).

The embodiment of Figures 10, 11 and 12 is similar in many ways to that of Figures 7, 8 and 9 but differs in the means for opening the capsule.

Those components of the device of Figures 10, 11 and 12 which correspond identically to those of Figures 7, 8 and 9 are denoted by the same reference numerals and will be described only briefly, if at all, in the following description.

Figure 10 shows that the capsule, in its opening position, is now aligned with a diameter of the chamber 24, but still has its longitudinal axis in the median plane of the chamber 24, i.e. in the plane which lies mid-way between the planar front and rear walls of the chamber as viewed in Figure 10 (the left hand and right hand walls as viewed in Figure 11). Again, the planar left hand wall is formed by a separate plug 29, and the planar right hand wall 30 is formed by a grid which serves to prevent the capsule and/or any fragments released upon perforation by the opening pins, from entering the respiratory tract of the user during inhalation. In the present embodiment the grid 30 is of a material which is electrically conductive or is otherwise anti-static. Preferably the material used is a conductive polymer. However, the grid may be of a metal such as stainless steel.

In this embodiment the pins 31 for opening the capsule are carried by a single push-button assembly 32

- 13 -

which is guided by a guide peg 33 and an extended guide peg 34 the end of which has a small diameter extension 35 to act as a latch release as will be described shortly.

Again a compression spring 36 is provided in order 5 to bias the push-button 32 to its outward position in which the two pins 31 are retracted from their respective guide ducts 37.

In order to allow the capsule to enter its opening recess, in which position it is illustrated in Figure 10, an 10 ejector slide 38 is mounted centrally within the body of the inhaler and is slidable axially under the control of an operating handle 39 (Figure 11). In order to hold the ejector in the retracted position shown in Figure 10, it includes a latch pip 40 which engages in an aperture 41 15 where it remains until ejected by the small diameter extension 35 serving as the latch release portion of the guide pin 34 for the push-button 32. Once the latch has been released, a compression spring 42 urges the ejector axially along the body of the inhaler to eject the capsule 20 from the diametrically extending recess into the main chamber 24, and at the same time the end-of-travel position of the ejector 38 is such that a concave arcuate leading surface 43 of the ejector fits flush with the peripheral wall of the chamber 24 in order to ensure that the capsule 25 will not be able to re-enter that capsule-opening recess during subsequent tumbling in the vertical airstream upon inhalation. It will however impact against the edges of a recess 25 which in this embodiment serves only to provide an irregularity to the peripheral wall of the swirling chamber 30 to provoke ejection of the powdered medicament from the capsule by percussive action.

Figure 10 shows, in broken lines, the location of a slot 44 (see also Figure 11) in the front casing 45 of the inhaler, to allow the operating handle 39 of the ejector 38 35 the degree of travel required for movement between the capsule-accepting position shown in Figure 10 and the

- 14 -

capsule-ejecting position (which is not shown in the drawings). It should be noted that the plane of section for Figure 11 is taken centrally of the slot 44.

The operation of the device shown in Figure 10, 11
5 and 12 will now be described.

Firstly the operating handle 39 of the ejector 38 is drawn to the position shown in Figures 10 and 11, in order to free the capsule-opening recess.

Then the front body portion 45 is removed from the
10 rear body portion 46 of the inhaler in order to allow insertion of the capsule into the capsule-opening recess.

The two body portions 45 and 46 are then fastened together again to close the chamber 24 ready for the capsule-opening operation.

15 It will of course be appreciated that throughout the above three operations the push-button 32 is held in its extended position shown in Figure 10, by virtue of the compression spring 36.

The push-button 32 is now inserted in order to
20 drive the two pins 31 into the capsule ends, and at the end of that insertion stroke the latch release extension 35 of the guide pin 34 will contact the latch pip 40 to release the latch and allow the ejector 38 to be driven forwardly to eject the capsule, under the action of the compression
25 spring 42.

With the capsule now positioned in the chamber 24, the user places his or her lips over the mouthpiece nozzle 27 and inhales in order to generate the swirling motion airstream within the chamber 24, giving rise to ejection of
30 the medicament from within the capsule, by the three-fold actions of pneumatic suction, centrifugal flinging, and percussive impact with the peripheral walls 24a, 25a of the chamber 24.

The user has an indication that the capsule has
35 been fully opened by the piercing operation in that unless the push-button 32 is inserted fully, to a position which

- 15 -

will correspond to adequate rupturing of the capsule ends by the needles 31, the latch release extension 35 of the pin 34 will not displace the latch pip 40 from its aperture 41 and hence the ejector will not be released to eject the capsule.

5 The user will be aware of this by the fact that the operating handle 39 of the ejector 38, also serving as an indicator, will not have displaced from the position shown in Figures 10 and 11. Only when this indicator has moved in order to signal ejection of the capsule should the operator
10 embark on the inhalation step.

Although in the above description it has been indicated that the embodiments of Figures 7 to 9 and Figures 10 to 12 both rely on separation of the front and rear body portions in their entirety in order to allow insertion of a
15 new capsule (and, incidentally, removal of the spent capsule from the last use), it will of course be understood that other arrangements are possible.

In Figures 10 to 12, the body portion 46 may only extend down as far as the end of the inhalation chamber
20 nearest the capsule opening means 31-34.

Alternatively, in both embodiments of pin opening device (Figures 7 to 9 and Figures 10-12), the plug 29 or the mouthpiece 27 and grid 30 section shown can be made to be removed in order to provide for access to the chamber 24
25 to allow removal of the spent capsule and equally insertion of a fresh capsule in either the capsule-opening recess 25 of Figure 7 or the capsule-opening recess in which the capsule is shown as being positioned in Figure 10. For this purpose the plug 29 or the mouthpiece and grid section may
30 be provided with any suitable means for enabling it to be removed, and the design of such means will be within the capability of the skilled expert in the art. Possibilities include screw threading on the plug 29 and the recess into which it fits, or a hinge, for example a thin film hinge, to
35 attach the plug 29 to the body of the inhaler.

It will be appreciated that each of the three

- 16 -

embodiments described in the present application has the feature of the capsule being opened in the inhaler, while oriented with its major axis in the median plane of the chamber in which the swirling inhalation airflow will cause 5 the capsule to tumble to discharge its contents. In the embodiment of Figures 1 to 6 this opening operation relies on physical separation of the capsule body from the capsule cap while positioned to one side of the chamber, in a position almost tangential to the airflow which is generated 10 during inhalation; in the embodiment of Figures 7 to 9 the opening position is again almost tangential to the airflow in the chamber, but opening is effected by axially moving penetrating pins at each end of the capsule; and in the embodiment of Figures 10 to 12 the capsule is positioned 15 diametrically of the chamber and opening is effected by transverse (i.e. radial) movement of pins but again operating at each end of the capsule.

It will be appreciated that in the embodiments of Figures 7 to 9 on the one hand and Figures 10 to 12 on the 20 other hand, although the capsule is opened by penetration at each end there is no question of airflow having to pass directly through the capsule as the sole means of removing the pulverulent contents. The development of the present invention has revealed that such a system would give too 25 high a pressure drop across the inhaler during the inhalation operation for a person with a disability of the respiratory function to inspire the contents efficiently, and bearing in mind that the capsule inhalation treatment is intended for those with some disability of the respiratory 30 function it is important to keep the pressure drop at a minimum, while aiming for as near as possible total removal of the contents during the inhalation. The present invention achieves such high efficiency of removal of the medicament from not only the capsule but also the inhalation 35 device as a whole, by (i) allowing random impact of the capsule ends with the walls of the chamber, and by (ii)

- 17 -

ensuring that the axis of symmetry of the capsule or of the individual separated capsule cap and body parts during the tumbling operation remains generally parallel to the median plane of the chamber so as to give the best possible
5 centrifugal action, and equally the optimum pneumatic suction on the interior of the capsule, during the inhalation operation. If the capsule were able to tumble into a different orientation where the axis of symmetry becomes anything other than parallel to the median plane of
10 the chamber, the degree of suction will be attenuated, or at least less reliable in strength. It is a feature of the inhalers disclosed in the present application that the contents of the capsule can be efficiently entrained in the airstream even at the relatively low airflow rates likely to
15 be associated with users with impaired respiratory functions.

There are various alternative possibilities for the configuration of the chamber, and it is felt that the adoption of a chamber in which the shape is not fully
20 cylindrical as shown in Figure 10 is preferable in that this will give rise to an increased likelihood of percussive impact on the walls of the recess 25 to tap the contents of the capsule clear of the ruptured capsule shell and capsule body and cap portions.

25 For the embodiments of Figures 7 to 9 and 10 to 12 it is desirable for the axial length of the chamber 24 (the minimum spacing between the front and the rear flat walls of the chamber) to be less than the axial length of the capsule, and preferably less than it by a margin sufficient
30 to ensure that there is no likelihood of the capsule being trapped in an inclined position. For the embodiment of Figures 1 to 6 it is preferable for the axial length of the chamber to be less than the axial length of the cap portion (this being shorter than the body portion) of the capsule,
35 for the same reason.

There are known inhalers using recesses formed in

- 18 -

the opposed walls which have been described herein as the front and rear walls of the chamber, where the capsule is held clear of the median plane of the chamber during capsule opening, or is even inserted in a capsule-opening recess
5 with the longitudinal axis of the capsule parallel to the axis of rotation of the swirling airflow during inhalation. Those constructions may result in a possibility for the capsule to become lodged in the capsule opening recess during the tumbling action, with the resultant holding of
10 the capsule and impeding of the capsule-emptying action during inhalation. It is considered an important optional feature of the present invention that the front and rear walls of the chamber are generally flat without such depressions, so that the likelihood of the capsule becoming
15 caught during inhalation is reduced if not negligible.

For the same reason the ejector 38 has the concave leading surface 43 which closes off the capsule-opening recess, thereby removing the possibility of the rounded ends of the capsule becoming caught against the sharp edges of
20 the capsule-opening recess, leading to the likelihood of the capsule jamming during inhalation.

As indicated above, the material used for the walls defining at least the swirling chamber, and preferably also the mouthpiece, may in all embodiments of the inhaler in
25 accordance with the present invention be one which is not likely to generate a high electrostatic charge which would cause the released pulverulent medicament to adhere to the surface of the body of the inhaler rather than passing outwardly through the mouthpiece nozzle.

30 Figure 13 shows a further embodiment of inhaler in which the capsule is to be opened by piercing with pins at its ends. This inhaler 60 has the mouthpiece 61 in the preferred embodiment hinged at 62 to the body portion 63 in which the inhalation chamber and the capsule opening means
35 are defined. Alternative means of detaching the mouthpiece from the body of the inhaler may be employed; for example, unscrewing, or twisting by means of a bayonet pin or pins

- 19 -

and arcuate slot may be provided for.

The capsule opening means is rotary in action and comprises a rotor having a recess 69 (Figure 15) to receive the capsule to be opened and a pusher member to eject the 5 pierced capsule from the recess 69, and the rotor itself is driven by a disc-like control wheel 64 operated manually. In a first, capsule-receiving position (illustrated in more detail in Figure 15) the capsule-receiving recess 69 in the 10 rotor is in register with a capsule insertion opening 65 in the body 63.

The inhalation chamber is positioned at the right hand end of the body 63, close to the point of junction between the body and the mouthpiece 61, and one of the air inlet openings 66 to that inhalation chamber can be seen in 15 Figure 14.

Figure 15 is a sectional view taken on the line 15-15 of Figure 13 and shows the mouthpiece clipped in its operative position by catch engagement between a projection 67 of the body and a corresponding projection 68 of the 20 mouthpiece.

Figure 15 also shows the capsule 5 in position in the capsule-receiving recess 69 in register with the capsule-inserting opening 65.

An arcuate wire clip 70 having a sharpened bent end 25 portion coaxial with the capsule 5 is secured to the end of the rotor 71 by projections 72 which trap the wire clip to rotate with the rotor.

A cam 73 cooperates with the wire 70 in a manner which will be more readily evident from Figures 18 and 19, 30 to drive the bent end portion of the wire clip axially into the capsule 5 held in the recess 69 to pierce the capsule.

It will of course be appreciated that there are in fact two such wires 70, one at each end of the rotor 71.

Figure 16 shows the rotor 71 after rotation in the 35 anti-clockwise direction through 180° to bring the capsule 5 with its axis passing through the cam 73.

- 20 -

As shown in Figure 19, in this position the sharpened end 74 of the bent portion 75 of the wire clip 70 has been pressed into the end of the capsule 5 by the operation of the cam 73 of the body 63 as the rotor 71 rotates.

Comparing Figures 18 and 19 will show that in the Figure 18 "capsule-receiving" position the wire clip 70 is not flat against the rotor but is in fact helical relative to the rotor end wall and that as the rotor rotates towards the Figure 19 position the point where the cam 73 bears against the back of the wire clip 70 gradually moves around the clip towards the bent end portion 75.

Figures 18 and 19 show that there is a similar cam 73' operating on the wire clip 70' at the opposite end of the rotor 71, in the same manner as described above for the cam portion 73.

Figure 17 is a sectional view taken on the line 17-17 of Figure 13 and shows the pusher member 76 within the rotor 71 to eject the capsule 5 into the inhalation chamber 77 after a further 90° of rotation of the rotor 71.

This pusher member 76 is biased in a radially outward direction by means of a helical compression spring 78.

Figure 17 also shows that, in common with the embodiments of Figures 1 to 6, 7 to 9 and 10 to 12, the inhalation chamber 77 is again defined by a generally flat right hand wall formed by the preferably electrically conductive grid 79 of the mouth piece 61 and a left hand wall 80 having an aperture through which a part of the circumference of the rotor 71 may project, but which is generally flat particularly when the capsule pusher member 76 is in the radially outermost position shown in Figure 17.

The dimension of the inhalation chamber between and perpendicular to the two flat walls 80 and 79 is again less than the axial length of a capsule 5 but greater than the diameter of the transverse cross-section of the capsule 5.

- 21 -

The airflow pattern through the inhalation chamber 77 can be best appreciated from Figure 20 which shows an inlet opening 81 entering the chamber 77 generally tangentially and the inlet opening 66 of Figure 14 which 5 also leads into an opening generally tangentially of the chamber 77.

Figure 20 also shows the capsule pusher member 76 of the rotor 71 and the recesses 85 at opposite sides of the swirling chamber 77 to provoke percussive ejection of the 10 medicament from the capsule.

In operation of the device shown in Figures 13 to 20, the operating disc 64 is first of all rotated to the Figure 15 position with the inhalation chamber 77 clear of the debris of any previous capsule. This clearance of the 15 chamber 77 can be achieved by swinging the mouthpiece 61 aside by means of the hinge 62.

The capsule 5 is then pressed through the insertion opening 65 and into the recess 69 against the action of the compression spring 78 and the disc 64 is then rotated 20 firstly to trap the capsule 5 behind the cylindrical wall of the body 63 and then further to bring the rotor 71 to the Figure 16 configuration where the end domes of the capsule cap portion and capsule body portion have been ruptured.

Further rotation of the disc 64 to bring the rotor 25 to the Figure 17 configuration will suffice to prepare the device for inhalation.

At this point the mouthpiece is inserted in the mouth of a patient and the patient inhales so that the air entering through the inlet ports 66 and 81 causes a swirling motion in the inhalation chamber 77 and rotates the capsule 30 rapidly about a transverse axis, in order to eject the pulverulent medicament from the capsule by a combined centrifugal action, a suction action, and a percussive action as the capsule strikes the peripheral wall of the 35 chamber 77.

Then, in order to prepare the device for the next

- 22 -

use, the mouthpiece is swung aside and the spent capsule removed, following which the disc 64 is then rotated by a further 90° from the Figure 17 position to the Figure 15 position to bring the capsule-receiving recess 69 into 5 register with the capsule-insertion opening 69.

Although in each of the above embodiments the first and second walls of the chamber, namely the opposed walls which together constrain the capsule or each separated capsule portion to maintain its axis of symmetry parallel to 10 the median plane of the chamber are shown throughout as flat, it is of course possible for these walls to be other than truly flat, while still maintaining a shape sufficiently close to the flat shape for allowing the desired capsule-constraining action to be effected. Where 15 the walls are not flat, it is the minimum spacing between these walls which is related to the dimensions of the capsule.

In the embodiment of Figures 1 to 6, the spacing between these first and second opposed walls defined by the 20 rear casing panel 4 and the grid 7 is less than the axial length of the capsule body portion 5a and less than the axial length of the capsule cap portion 5b.

In the embodiments of Figures 7 to 9 and 10 to 12 the spacing between these first and second opposed walls is 25 less than the total axial length of the capsule. This preferred feature guards against any possibility of the capsule becoming jammed in an oblique configuration where the roughness of the grid might assist in holding the capsule and preventing it from rotating freely in the 30 swirling airstream.

- 23 -

CLAIMS

1. An inhaler which comprises a chamber defined by (a) first (4) (29) (80) and second (7) (30) (79) generally parallel spaced opposed walls defining a median plane of said chamber mid-way therebetween, and between which parallel spaced walls the capsule (5) can fit with its longitudinal axis generally parallel to said first and second walls but in any angular orientation, and (b) at least one peripheral wall; an exhaust nozzle (6) (27) (61) through which air can be exhausted from said chamber by inhalation; at least one air inlet (9, 10) (26) (66, 81) arranged in relation to the exhaust nozzle to generate in the chamber during inhalation an airflow rotating about an axis generally perpendicular to said first and second walls; and holding means (12, 13) (25) (38, 82) (69, 76) in the inhaler in association with means (13, 14) (21) (31) (74) operable from outside the closed chamber for opening a capsule while held in the holding means, wherein the holding means are effective to hold a capsule having a length greater than the minimum spacing between first and second walls and less than the minimum cross-sectional dimension of said chamber when viewed parallel to said axis of rotation and is configured to hold a capsule with its axis of symmetry substantially coincident with the median plane of said chamber, and to hold a capsule having a diameter less than said minimum spacing between the first and second walls; characterised in that the holding means are effective to hold said capsule with the longitudinal axis of the capsule perpendicular to said axis about which the inhalation air rotates.

2. An inhaler according to claim 1, characterised in that said capsule opening means (13, 14) comprises means for physically separating the cap portion (5a) of the capsule from the body portion (5b) of the capsule whereupon said separated cap and body portions are able to tumble in

- 24 -

the chamber during inhalation.

3. An inhaler according to claim 2, characterised in that the minimum spacing between said first and second walls of the chamber is less than the axial length of said 5 capsule cap portion (5a) and than that of said capsule body portion (5b).

4. An inhaler which comprises a chamber defined by (a) first (29) (80) and second (30 (79) generally parallel spaced opposed walls between which the capsule (5) 10 can fit with its longitudinal axis generally parallel to said first and second walls but in any angular orientation, and (b) at least one further wall; an exhaust nozzle (27) (61) through which air can be exhausted from said chamber by inhalation; at least one air inlet (26) (66, 81) arranged 15 in relation to the exhaust nozzle to generate in the chamber during inhalation an airflow rotating about an axis generally perpendicular to said first and second walls; and a recess (25) (82) (69) in the inhaler in association with means (21) (31) (74) for opening a capsule while held in the 20 recess with the longitudinal axis of the capsule perpendicular to said axis, wherein the opening means are effective to open a capsule having a length greater than the minimum spacing between said first and second walls and less than the minimum cross-sectional dimension of said chamber 25 when viewed parallel to said axis of rotation, and to open a capsule having a diameter less than said minimum spacing between the first and second walls; characterised in that the chamber is non-circular (at 25) (at 85) and is able to allow the capsule to rotate freely about its transverse axis 30 under the influence of the inhaled airstream and to impact against said at least one further wall in order to increase the likelihood of ejection of the medicament from within the capsule.

5. An inhaler according to claim 1, characterised 35 in that said means for opening the capsule comprise means (21) (31) (74) for rupturing the capsule to permit discharge

- 25 -

of the contents of the capsule while the capsule spins in the rotational airflow during inhalation, and the holding means comprise a recess (25) (82) (69) configured to receive a said capsule for rupturing.

5 6. An inhaler according to claim 4, characterised in that said means for opening the capsule comprise means (21) (31) (74) for rupturing the capsule to permit discharge of the contents of the capsule while the capsule spins in the rotational airflow during inhalation, and said recess 10 (25) (82) (69) is configured to receive a said capsule for rupturing.

15 7. An inhaler according to claim 6, characterised in that the minimum spacing between said first and second walls of the chamber is less than the axial length of the 20 capsule to be held by said recess during opening by said opening means and to be tumbled in said chamber during inhalation.

25 8. An inhaler according to claim 7, characterised in that the minimum spacing between said first and second walls is less than the axial length of the cylindrical part of a said capsule.

30 9. An inhaler according to any one of claims 6 to 8, characterised in that said capsule holding means receive the capsule in a position with its longitudinal axis generally tangentially of the chamber, while the capsule is opened, whereupon the capsule is released for extraction from said holding means by the subsequent vortical inhalation airstream.

35 10. An inhaler according to any one of claims 5 to 8, characterised in that the capsule holding recess extends generally diametrically of said chamber, and said rupturing means comprise means (31) for piercing the ends of a capsule received in said recess with its longitudinal axis extending diametrically of the chamber, and further including means (38) for ejecting the thus pierced capsule from said recess into the chamber for tumbling during subsequent inhalation.

- 26 -

11. An inhaler according to claim 10,
characterised in that said capsule ejector includes a
capsule-ejecting end face (43) which smoothly conforms to
the said at least one further wall when the ejector is in a
5 position corresponding to displacement of the capsule having
been achieved.

12. An inhaler according to any one of claims 1 to
8, and further characterised by including means for closing
said air inlets until inhalation is required, and wherein
10 said capsule opening means are effective to open the capsule
only while said air inlets are closed.

13. An inhaler according to any one of claims 1 to
8, characterised in that the exhaust nozzle is eccentric in
relation to said chamber, whereby the capsule spins in the
15 inhalation airflow with random collisions against the
further walls of said chamber.

14. An inhaler according to any one of claims 4 to
8, characterised in that said chamber is rendered non-
circular by virtue of said recess (25) extending
20 tangentially of the chamber for receiving the capsule to be
ruptured by said rupturing means.

15. An inhaler according to claim 1, characterised
in that the capsule opening means comprise a recess
extending generally diametrically of said chamber, and said
25 rupturing means comprise means for piercing the ends of a
capsule received in said recess with its longitudinal axis
extending diametrically of the chamber, and further
characterised by including means for ejecting the thus
pierced capsule from said recess into the chamber for
30 tumbling during subsequent inhalation.

16. An inhaler according to any one of claims 4
and 6 to 8, characterised in that said capsule opening means
comprise a capsule-receiving rotor (71) rotatable about an
axis parallel to the median plane of said chamber, and
35 having a capsule recess (69) to receive a capsule with its
longitudinal axis parallel to the axis of rotation of said

- 27 -

rotor, and capsule-rupturing pins (74) carried by said rotor and driven to rupture said capsule during rotation of the rotor between a capsule-receiving position and a capsule-releasing position when the capsule is released into said 5 chamber.

17. An inhaler according to claim 16, characterised in that said capsule-rupturing pins comprise bent end portions of arcuate wires (70, 70') at opposite ends of said rotor, with said arcuate wires extending 10 generally around the axis of rotation of said rotor and said bent pin-defining end portions coaxial with said capsule-receiving recess, and in that said inhaler further includes stationary cams (73, 73') which engage said arcuate portions to drive the capsule-rupturing end portions axially of the 15 capsule-receiving recess.

18. An inhaler according to any one of claims 1 to 8, characterised in that the chamber has walls defined of an anti-static member having a surface resistivity of less than 10^{12} Ohms.

19. An inhaler comprising a mouthpiece (6) (27) (61); and a swirling chamber to receive a container (5) which can be agitated, when open, in an inhalation airstream to release powdered medicament from the interior of the container; characterised in that the chamber has walls 25 defined of an anti-static member having a surface resistivity of less than 10^{12} Ohms.

20. An inhaler according to claim 19, characterised in that said mouthpiece has internal walls defined by a member having a surface resistivity of less 30 than 10^{12} Ohms.

21. An inhaler according to claim 20, characterised in that said swirling chamber is integrally formed with said mouthpiece.

22. A device according to any one of claims 19 to 35 21, characterised in that the swirling chamber walls have their inner and outer faces given the same low surface

- 28 -

resistivity.

23. An inhaler according to any one of claims 19 to 21, characterised in that said swirling chamber is defined by front and rear walls of which said front wall has 5 said mouthpiece therein and said rear wall has an inner surface with a surface resistivity of less than 10^{12} Ohms.

24. An inhaler according to any one of claims 19 to 21, and further characterised by including an electrically conductive or otherwise anti-static grid 10 disposed between said chamber and said mouthpiece through which grid the inhalation airflow and entrained medicament pass.

25. An inhaler according to any one of claims 19 to 21, characterised in that the or each said member having 15 a surface resistivity of less than 10^{12} Ohms is a polymeric material having a surface resistivity of less than 10^{12} Ohms.

26. An inhaler according to claim 25, characterised in that said polymeric material includes one 20 or more additives to lower the surface resistivity of said material.

27. An inhaler according to claim 26, characterised in that said additives include an additive of carbon or metallic particles as filler.

28. An inhaler according to any one of claims 19 to 21, characterised in that said surface resistivity of less than 10^{12} Ohms is derived by application of a surface coating to the associated inhaler member.

29. An inhaler according to any one of claims 19 to 21, characterised in that said components having a surface resistivity of less than 10^{12} Ohms are formed by injection moulding of a polymeric material of low surface resistivity.

30. An inhaler according to any one of claims 19 to 21, characterised in that the surface resistivity is less 35 than 10^8 Ohms.

- 29 -

31. An inhaler according to any one of claims 19 to 21, characterised in that said swirling chamber is non-circular in cross-section when viewed along the axis of rotation of the inhalation air, whereby a capsule in the 5 chamber may rotate under the influence of the inhaled airstream and may impact the non-circular peripheral wall of the chamber.

1/7

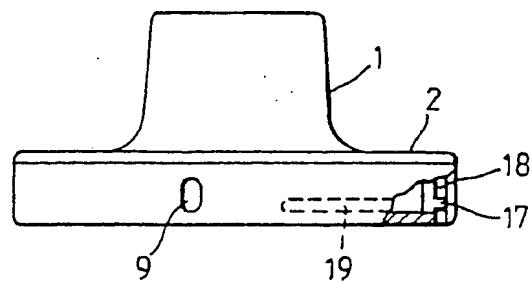
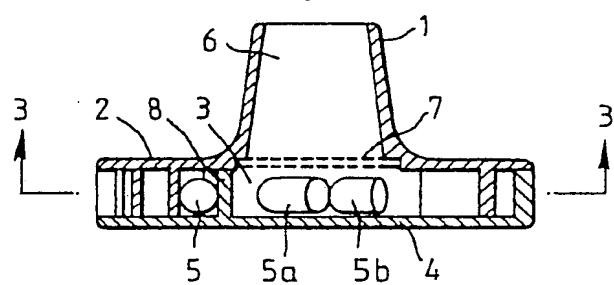
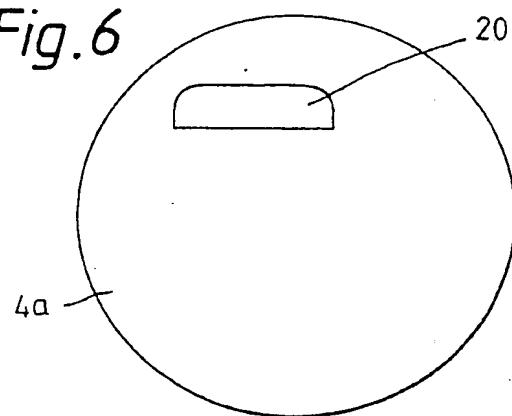
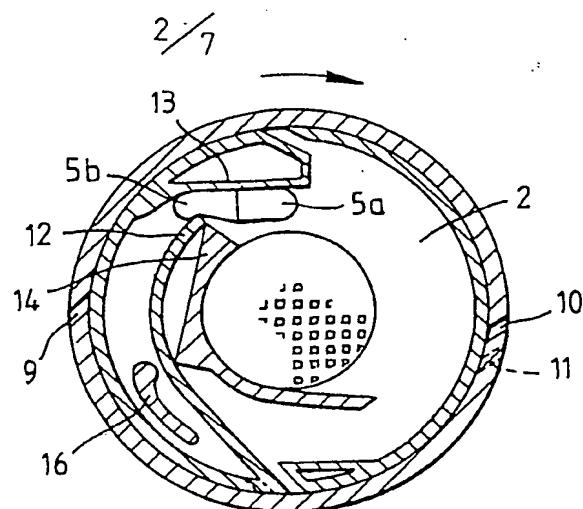
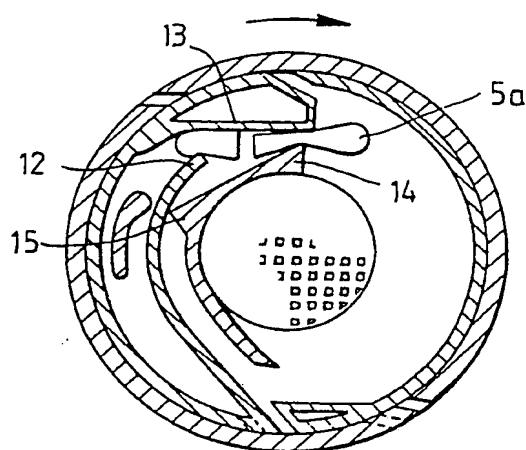
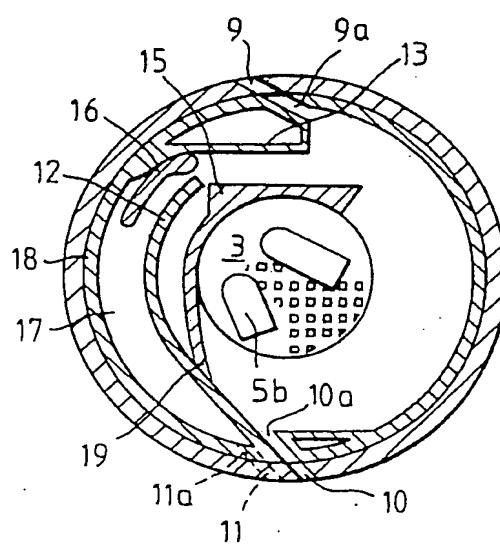
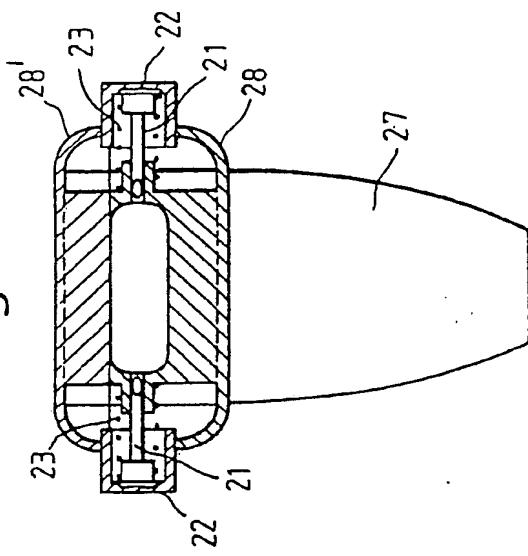
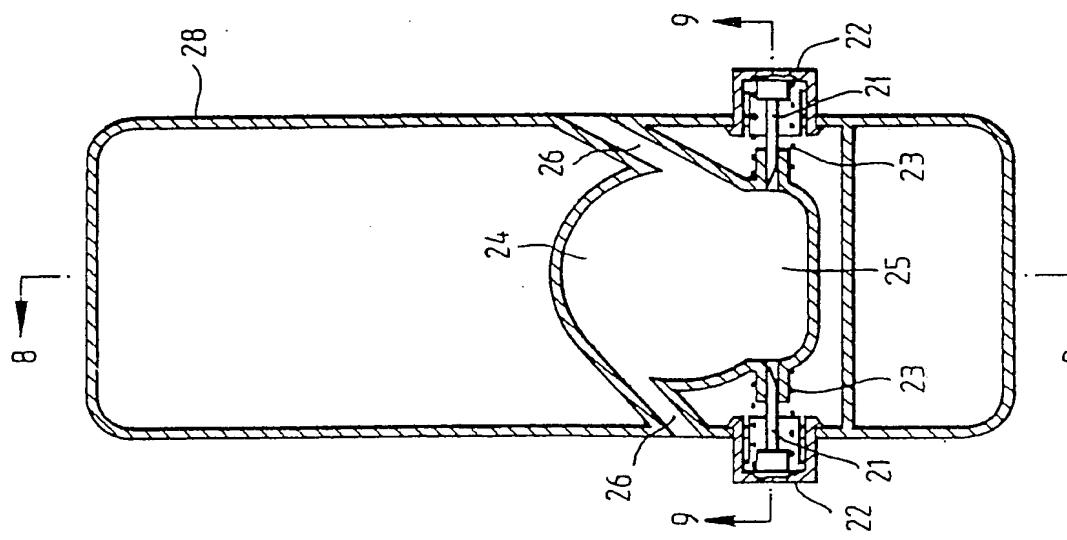
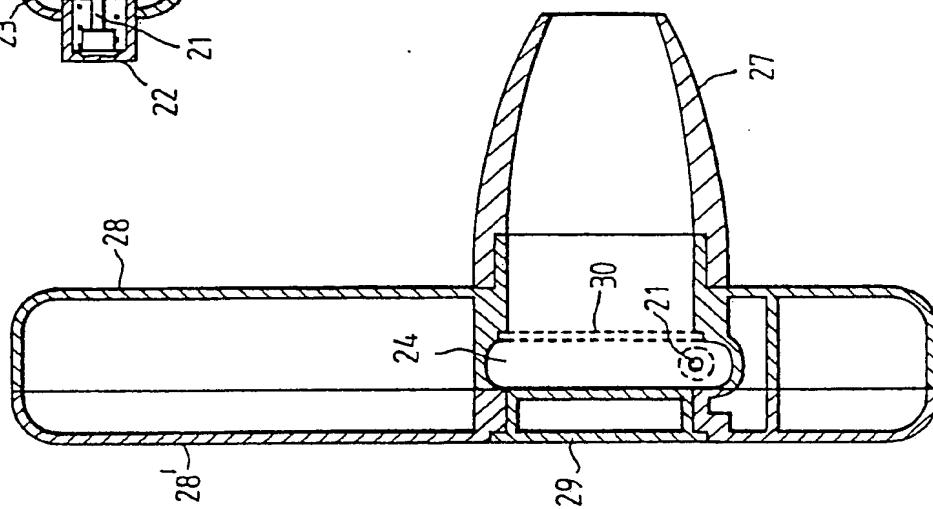
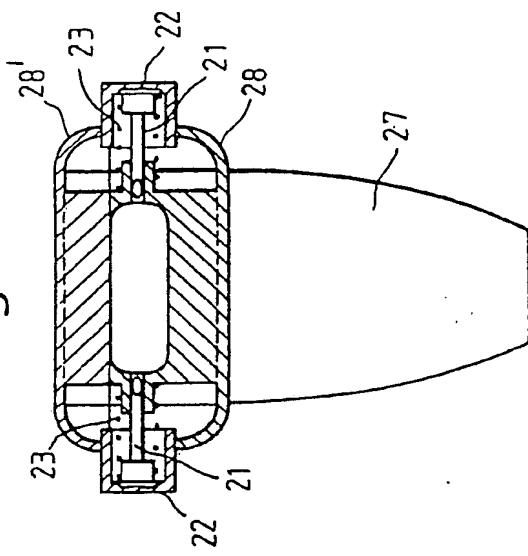
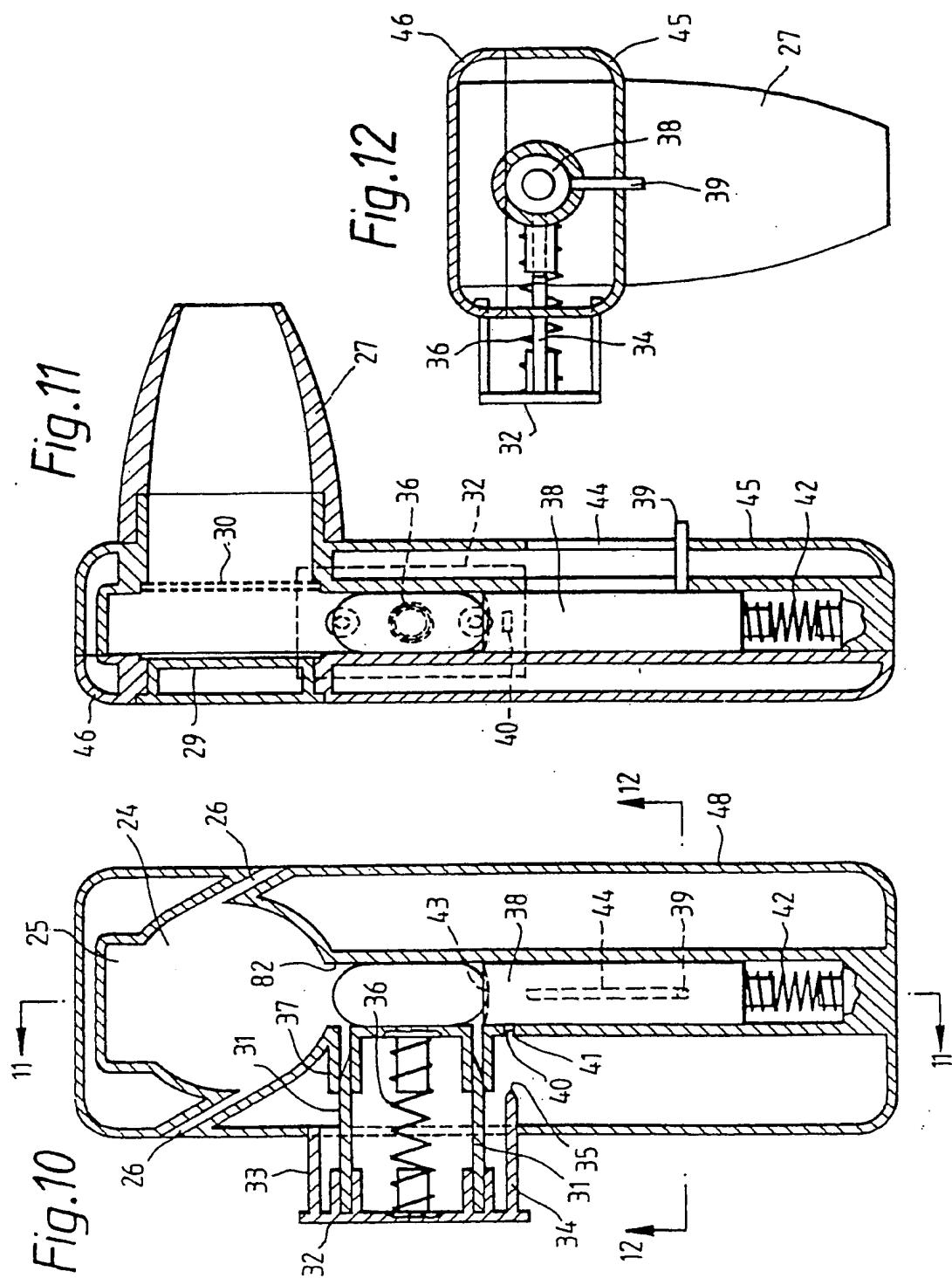
Fig.1*Fig.2**Fig.6*

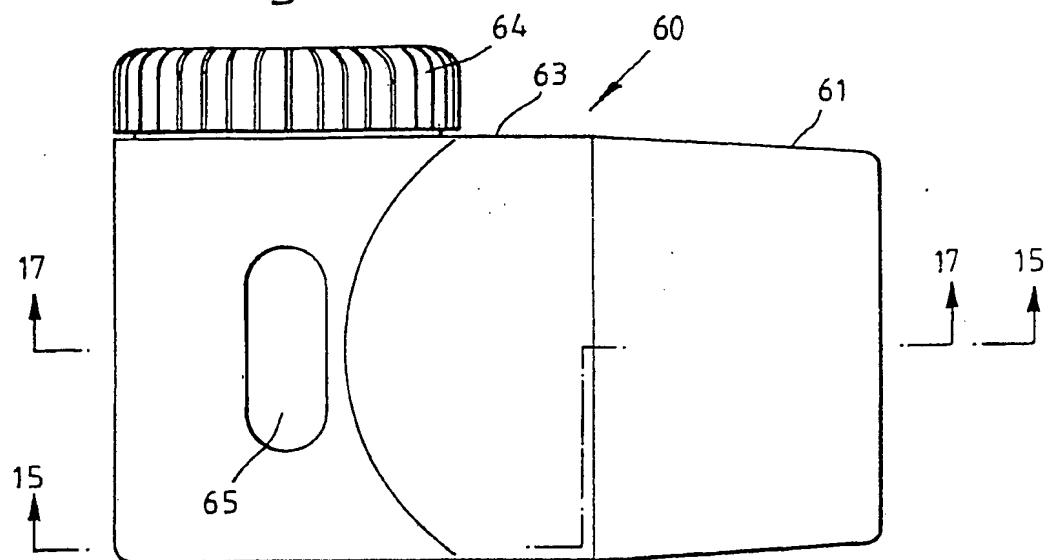
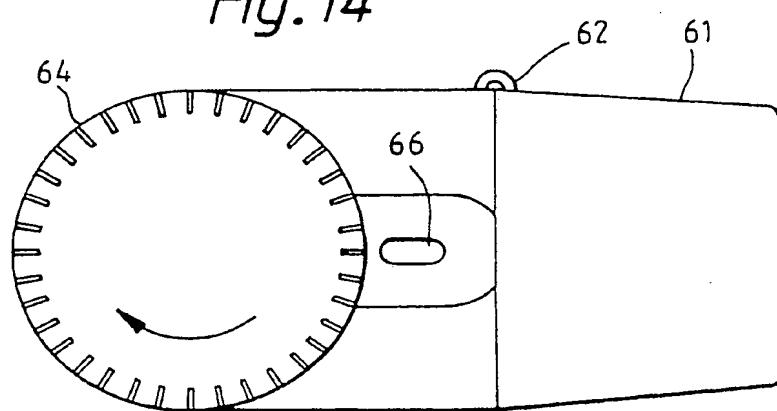
Fig. 3*Fig. 4**Fig. 5*

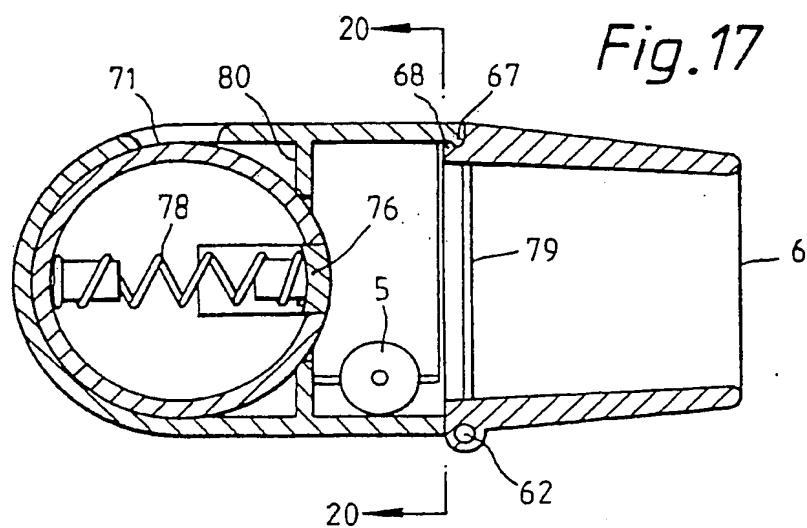
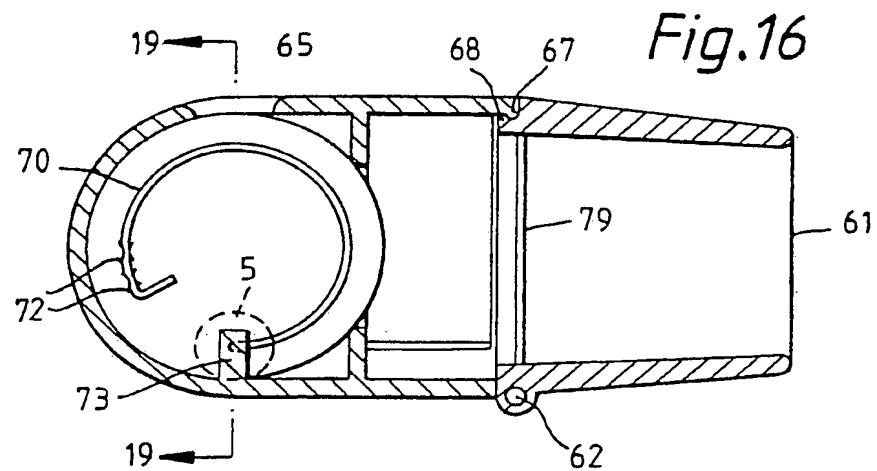
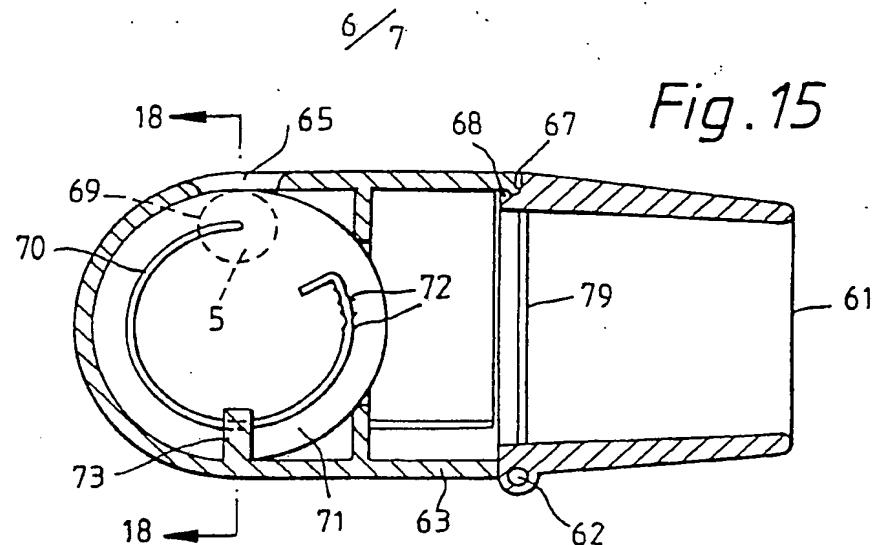
3/7

Fig. 9*Fig. 7**Fig. 8**Fig. 9*



5/7

Fig. 13*Fig. 14*



7/7

